Ash Stevens™

Legislative Proposal: MI SB 540, SB 541 and HB 5132, HB 5133 directs insurance companies that cover cancer to cover orally administered anticancer medications on a basis no less favorable than intravenously administered anticancer medications and further requires that the patient cost sharing for intravenous anticancer medications cannot be increased to achieve compliance.

The principle benefit is that the legislation pursues the best outcome for patients by ensuring they have access to the most appropriate therapy when prescribed by their physicians. As a manufacturer of pharmaceutical products, an employer in Michigan, and a member of the Michigan life sciences industry, Ash Stevens sees additional benefits to Michigan's life science economy and overall business climate.

Unless public policy supports access to new therapies, the opportunity to grow the economy with life science manufacturing jobs and related spin-off industries may be lost. Through innovative technology, the discovery pipelines increasingly introduce new oral anticancer medications creating a demand for their manufacture and production of indirect goods and services. These manufacturing demands create precious employment opportunities in an economic climate that offers few jobs and even fewer in the manufacturing sector. Fostering manufacturing is an important goal to restoring the economy; to foster it in the life science arena where high level income positions are created is a significant advantage for Michigan's economy.

Another potential loss to Michigan's economy if public policy does not reflect state of the art science is the viability of research and development entities, whether they be through university laboratories, small start-up companies, or long established pharmaceutical manufacturers. Currently, Michigan is fortunate to enjoy a robust life science community dedicated to researching disease states for which there is no cure. If patients do not have access to state of the art therapies, then the incentive for scientists to develop more effective treatments disappears. It is paramount to support and encourage Michigan research and development by establishing public policy that reflects the innovations and progress achieved by the life science community.

Ash Stevens strongly supports SB 540, SB 541 and HB 5132, HB 5133 not only because it is the right thing to do for patients but because it establishes fair public policy that supports the growth of employment opportunities for stakeholders in the health care and life sciences arena.

Best Regards.

Stephen A. Munk, Ph.D.
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The Honorable Gail Haines
Committee Chair
124 North Capital Ave
P.O. Box 30014
Lansing MI 48909-7514

Subject: Support of SB 540 and SB541 (sponsored by Senator Kahn) and HB 5132 and HB 5133 (sponsored by Representative Haines): Oral anticancer medication access

Dear Representative Haines;

I am writing to you to express my support for SB 540, SB 541, HB 5132 and HB 5133. By way of background, oral anticancer medications have been available for several decades, and they are becoming an increasingly common treatment alternative for cancer patients. Many oral medications are targeted for specific types of cancer and this is the only appropriate treatment method. Both private and public insurance plans often require enrollees to pay higher out-of-pocket costs for oral medications than for intravenous medications, sometimes as much as $2200 to $7900 per month. Unfortunately, the higher out-of-pocket costs often result in patients abandoning the prescription or using a treatment method that is not the targeted, thus optimal, treatment that the physician prescribes for the patient.

The inconsistency between patient cost sharing requirements for intravenous and oral anticancer medications can largely be attributed to the fact that intravenous medications are usually covered as a medical benefit, while oral medications are usually covered as a pharmacy benefit. Medical and pharmacy benefits are commonly provided by separate benefit plans that are administered by separate and distinct entities; specifically, medical benefit plans are typically administered by an insurer, health maintenance organization, or third party administrator (TPA), while prescription drug plans are typically administered by a pharmacy benefit manager (PBM). The patient's cost burden for an intravenous medication is usually therefore determined by the cost sharing requirements of the patient's medical benefit plan, while the patient's cost burden for an oral medication is determined by the cost sharing requirements of the patient's pharmacy benefit plan.

ELIMINATE CANCER TREATMENT INEQUITIES

WHEREAS, the National Black Caucus of State Legislators (NBCSL) has a strong commitment towards equality in treatment of diseases and conditions; and

WHEREAS, according to National Cancer Institute of Researchers, African Americans have a 33 percent higher risk of dying of cancer than Caucasians;

WHEREAS, the emergence of clinically proven safe and effective orally and intravenously administered anticancer medications has significantly increased treatment options for patients; and

WHEREAS, oncologists have significantly improved the care of patients by utilizing both orally and intravenously administered chemotherapy medications; and

WHEREAS, greater patient out-of-pocket costs create a barrier for oral anticancer therapies covered under the pharmacy benefit of a health care plan; and

WHEREAS, the NBCSL does not support one medication over another, but supports the best option for the patient as well as a patient's right to be informed and chose his or her treatment; and

WHEREAS, just as an example of where inequities exist; intravenously administered anticancer medications are typically covered under a health care plan's medical benefits and require only an office visit copayment, but orally administered chemotherapy medications are typically covered by the prescription drug benefit and require significantly higher copayment or coinsurance to fill the prescription at a pharmacy.

NOW, THEREFORE BE IT RESOLVED, that the NBCSL supports the elimination of cost barriers for cancer patients to access chemotherapies; and

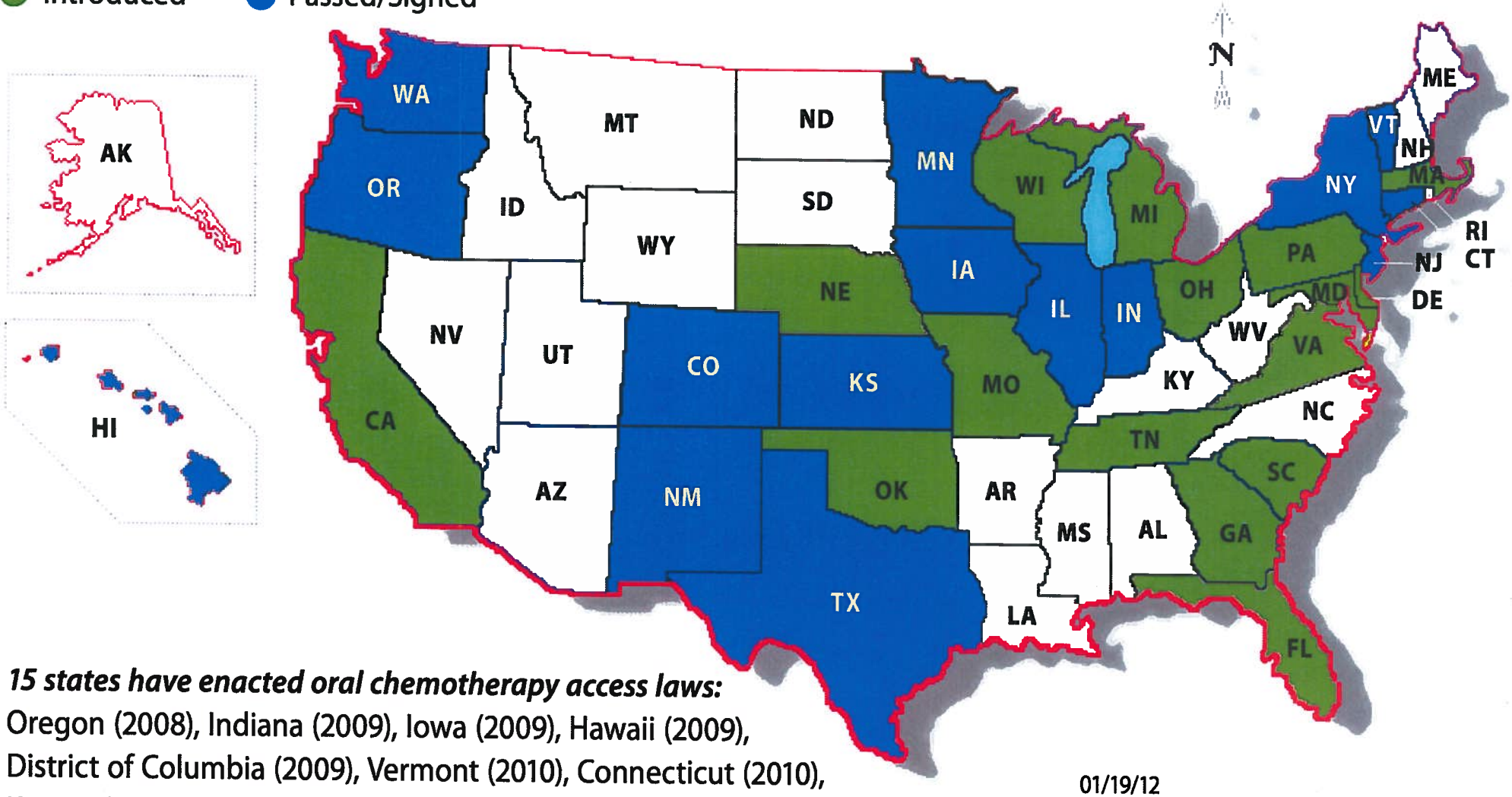
BE IT FURTHER RESOLVED, that the NBCSL supports patients being given the best medication given their health status and not their financial status, and recognizes that a doctors decision given the specifics of a given case need to reach the optimal solution for the patient; and

NOW, BE IT FINALLY RESOLVED, the NBCSL encourages each member to investigate legislation in their state that will seek to eliminate cancer patient payment inequities for oral cancer treatments.

SPONSOR(S): Representative Edna Brown (OH) and Delegate Shirley Nathan-Pulliam (MD)
Committee of Jurisdiction: Health and Human Services Policy Committee
Certified by Committee Chair: Representative Joe Armstrong (TN)
Ratified in Plenary Session: Ratification Date is December 4, 2009
Ratification is certified by: Representative Calvin Smyre (GA), President

Oral Chemotherapy Access Legislative Landscape – January 2012

Introduced Passed/Signed



15 states have enacted oral chemotherapy access laws:
Oregon (2008), Indiana (2009), Iowa (2009), Hawaii (2009),
District of Columbia (2009), Vermont (2010), Connecticut (2010),
Kansas (2010), Colorado (2010), Minnesota (2010),
Illinois (2011), New Mexico (2011), Texas (2011),
New York (2011), Washington (2011) and New Jersey (2012).

01/19/12

Ensuring Equity in Oncology Drug Benefits
What is being said about Oral Chemotherapy Parity

Indiana Department of Insurance
In response to inquiries made by Senator Becker and Representative Welch regarding the 2009 enactment of the oral chemotherapy parity law (Public Law 46)
August 2010

"There is no evidence of 'cost-shifting.'"

"The Chief Deputy of Consumer Services confirmed there have been no consumer complaints against health plans for noncompliance or changes to an existing benefit plan due to the parity law."

"There were initial concerns raised by some [insurance] carriers regarding a potential increase to accommodate the new mandate; however, no increase has materialized at this time."

Oregon Insurance Division of the Department of Consumer & Business Services
In response to inquiries concerning the enactment of the 2008 oral cancer drug parity law

"There is no evidence that implementation of the state's oral cancer drug parity law has increased health insurance premiums."

Report to Agency for Health Care Administration and Legislative Committees of Substantive Jurisdiction; Florida HB 623
Submitted by the American Cancer Society, Florida Division, and the International Myeloma Foundation
November 2011

"As to insurance premiums, because of the variety of plans and plan coverages within its cohort, the 2010 Milliman study calculated that the cost of implementing chemotherapy parity would be less than $0.50 per member per month for most plan designs. However, the State of Indiana has implemented legislation similar to that proposed in Florida, and the Indiana Department of Insurance has confirmed that the new law has not resulted in increased health insurance premiums."

Vermont Department of Banking, Insurance, Securities and Health Care Administration Pre-implementation Study
Study conducted in preparation to the 2010 passage of an oral cancer drug parity bill
January 2009

The study found that the states which had passed the laws reported, at most, a "negligible" impact on insurance rates. Similarly, a state-conducted survey of insurers "provided no indication of significant rate increases as a result of the legislation."

Kansas State Employees Health Care Commission's Orally Administered Anticancer Drug Report

Report was required by the legislature per 2010 Senate Substitute for House Bill No. 2160, February 2011

"There was minimal impact to the health plan finances to provide this pilot as the State Employee Health Plan (SEHP) has historically provided coverage for orally administered anticancer medications under the pharmacy program. To comply with this requirement under the medical plan it was necessary to make some minor benefit modifications. The SEHP recommends these orally administered anticancer drugs continue to be covered by the plan."

New Jersey Letter from Governor Christie in response to a constituent letter

Concerning Senate Bill No. 1834
February 2012

"Thank you for writing to the Lieutenant Governor to express your support for Senate Bill No. 1834, which would require health insurers to cover oral anticancer medications on a no-less-favorable basis than intravenous anticancer medications. I appreciate hearing from you on this important topic.

This bill will help to reduce the discrepancies in insurance coverage of oral chemotherapy. Prior to this bill, many insurance carriers required greater cost-sharing by the patient for oral chemotherapy. This bill provides that coverage for expenses for prescribed, orally administered anticancer medications should not be subject to any prior authorization, dollar limit, copayment, deductible or coinsurance provision that does not apply to intravenously administered or injected anticancer medications. I believe that cancer patients should have access to the most efficacious treatments without concern for costs, which is why I signed this bill into law on January 17, 2012."

Prices of Oral Chemotherapies as Compared to IV Chemotherapies

In the debate over oncology parity legislation, many have asked questions about the prices of oral chemotherapies relative to the prices of IV/injectable chemotherapies. This document provides an overview of the current prices of the most recent oral and IV therapies. These agents were all approved by the FDA in the past 10 years (since January 2000)

The prices in the chart below reflect current monthly mean (average) and median wholesale acquisition costs (WAC[i]) for 31 anti-cancer agents.[ii] These prices represent only the actual drug costs. They do not include physician administration or monitoring costs.

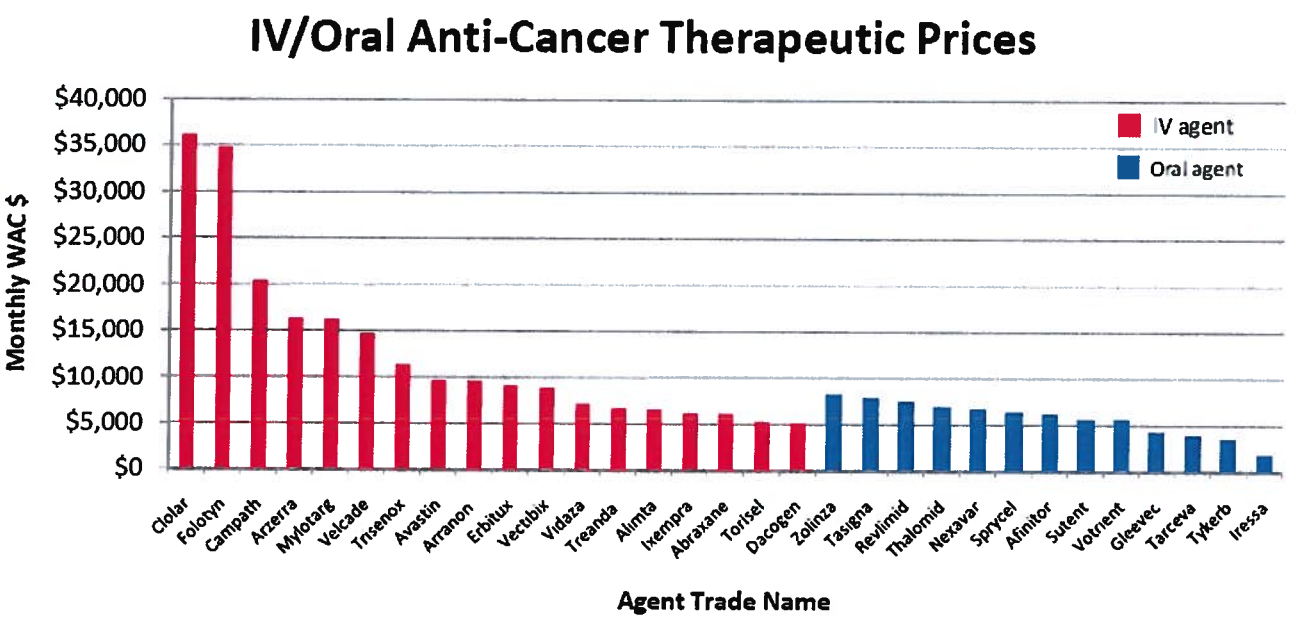
In summary the results are:

	IV agents	Oral agents
Number of Agents	18	13
Mean monthly WAC cost	$12,830	$5,699
Median monthly WAC cost	$9,395	$6,190

Conclusion:

- **On a cost per month basis, oral chemotherapy agents, in aggregate, are not more expensive than IV agents; in fact oral agents appear to be 35%-55% less expensive than the IV agents.**

The bar chart below illustrates each of the selected 31 oral and IV agents' WAC price:



[i] Wholesale Acquisition Cost (WAC) is the listed price to wholesalers and warehousing chains, not including prompt pay, stocking or distribution allowances, or other discounts, rebates or chargebacks. Listed price may not represent prices charged to other customers, including specialty distributors.

[ii] Monthly WAC prices February 2010 reference: Wolters Kluwer Health, Inc. February, 2010.

Examples of Administration Costs Associated with IV/Infused Chemotherapy

CPT Code	Description	Average Reimbursement
96360	Hydration iv infusion, initial	$59.43
96361	Hydration iv infusion, add-on	$15.98
96365	Ther/proph/diag iv infusion, initial	$73.72
96366	Ther/proph/diag iv infusion add-on	$22.61
96367	Tx/proph/dg additional sequence iv infusion	$34.12
96368	Ther/diag concurrent infusion	$20.17
96372	Ther/proph/diag injtial, sc/im	$24.00
96374	Ther/proph/diag injtial, iv push	$58.03
96375	Tx/pro/dx injtial new drug add-on	$23.65
96401	Chemo, anti-neopl, sq/im	$75.75
96402	Chemo hormon antineopl sq/im	$36.21
96409	Chemo, iv push, single drug	$117.17
96411	Chemo, iv push, addl drug	$65.70
96413	Chemo, iv infusion, 1 hr	$151.68
96415	Chemo, iv infusion, addl hr	$32.37
96416	Chemo prolong infuse w/pump	$167.58
96417	Chemo iv infusion each additional sequence	$75.12
96450	Chemotherapy, into CNS	$226.35
96521	Refill/maintenance, portable pump	$138.08
96523	Irrigation drug delivery device	$26.43
96542	Chemotherapy injection	$143.75

CPT (Current Procedural Terminology) codes are numbers assigned to every task and service a medical practitioner may provide to a patient including medical, surgical and diagnostic services. They are then used by insurers to determine the amount of reimbursement that a practitioner will receive from an insurer. In IV/infused chemotherapy, these costs would be incurred in addition to the cost of the drug itself. Health care providers utilize multiple CPT codes each time a patient undergoes an infusion.

**It is important to note that each health care facility negotiates its own reimbursement rates with health insurers. These average reimbursement rates listed are based on Medicare reimbursement rates. As the largest U.S. purchaser and regulator of health care, Medicare exerts a major influence on the rest of the health care system. Its reimbursement and coverage policies have been widely adopted by private insurers and other public programs.*

CRAIN'S DETROIT BUSINESS
Detroit and Southeast Michigan's premier business news and information website

November 27, 2011 5:30 PM

OTHER VOICES: Give cancer pills equal insurance coverage

By Gerold Bepler


Gerold Bepler

Imagine you've received a cancer diagnosis and the best -- possibly only -- treatment that will manage your disease has limited side effects, lets you continue working, and can be administered at home. But it is financially out of reach -- because it's a pill.

This occurs every day because many health plans do not cover oral anti-cancer medications at the same level as intravenous or infused anti-cancer medications given in a doctor's office or hospital.

Cancer is increasingly being treated with targeted medications. For several cancers, long-term disease control is possible even when a cure is not. Decades of research into cancer cell biology have identified pathways to cancer cell survival and growth. The latest anti-cancer drugs are targeted chemicals that inhibit or alter these cellular pathways.

Targeted drugs do not have the usual side effects, such as nausea and hair loss. Patients are able to work, care for their children and lead relatively normal lives while fighting their disease.

Unlike traditional (intravenous) chemotherapy, many of these new drugs only come as

pills. Researchers estimate that between 25 percent and 35 percent of promising anti-cancer drugs in development are oral and can be taken at home. We should be celebrating these new advancements that are changing the future of cancer medicine.

But these new drugs are out of reach for many patients, even if they have "good" insurance coverage. Traditional intravenous chemotherapy is administered at a physician's office or in a hospital infusion clinic. Costs include the necessary treatment as well as the overhead to administer it. Pill chemotherapies are obtained by patients as prescription drugs from their oncologists and can be taken at home.

Many health insurance plans require patients to pay extremely burdensome out-of-pocket costs for expensive oral anti-cancer medications, while intravenous anti-cancer medications, although still costly, are universally covered under patients' hospital care benefits, with a negligible co-pay.

For most patients, paying for oral cancer drugs is simply impossible. The psychological impact on patients dealing with a cancer diagnoses and huge out-of-pocket costs are devastating. It's time that insurance plans support modern cancer care.

Michigan residents can contact their state legislators and ask them to pass the Oral Chemotherapy Access bills (Senate Bills 540 and 541 and House Bills 5132 and 5133.) Michigan can join 14 other states and the District of Columbia in ensuring that patients have access to all anti-cancer medications, regardless of how they're administered, if the Legislature passes this legislation.

This common-sense legislation would not mandate coverage of chemotherapy, but it would require that health plans that cover traditional chemotherapy ensure access to all chemotherapies, regardless of how the medication is administered.

Passing The Oral Chemotherapy Access bills is the right thing to do.

Gerold Bepler, M.D., Ph.D., is president and CEO of the Barbara Ann Karmanos Cancer Institute in Detroit.